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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,506	11/20/2003	Brian Anthony Whittle	WHIT3001C2JDB	5627
23364	7590	05/18/2007		
BACON & THOMAS, PLLC 625 SLATERS LANE FOURTH FLOOR ALEXANDRIA, VA 22314			EXAMINER TATE, CHRISTOPHER ROBIN	
			ART UNIT 1655	PAPER NUMBER
			MAIL DATE 05/18/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/716,506	Applicant(s) WHITTLE ET AL.	
	Examiner Christopher R. Tate	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2007 and 07 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 9-16 is/are pending in the application:
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 9-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>0507</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>0407</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

The amendment filed 20 February 2007 and the Terminal Disclaimer filed 07 March 2007 are acknowledged and have been entered. Claims 1-4 and 9-16 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 15 and 16 stand rejected under 35 U.S.C. 112, first paragraph for the reasons set forth in the previous Office action which are restated below.

The specification, while being enabling for a composition for treating atopic eczema, non-atopic eczema and psoriasis comprising particular combinations of demonstrated herbals (such as the various particular combinations recited in original claim 8 - now canceled), does not reasonably provide enablement for a composition having such a therapeutic effect comprising any and all combinations of herbals from among those instantly recited, or for treating any and all undefined atopic disease with even the instantly demonstrated particular herbal combination. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants have reasonably demonstrated that particular combinations of the recited herbals are useful for treating atopic eczema, non-atopic eczema and psoriasis. However, the claims encompass the use of any and all of the vast number of herbal permutations defined by

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the claims for such treatment, as well as for treating any and all undefined atopic diseases with such combinations, which is clearly beyond the scope of the instantly demonstrated invention.

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to prepare and utilize an herbal composition having the instantly claimed functional effect(s) other than the particular demonstrated herbal combinations (such as recited in original claim 8) for treating atopic eczema, non-atopic eczema and psoriasis (but not for treating any and all undefined atopic diseases).

Applicants' arguments concerning the above rejection have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicants argue that claim 1 has been amended so as to include the limitations of claim 1 (as suggested by the Examiner). However, claims 15 and 16 have not been amended in such a manner. Accordingly, for the reasons set forth above, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to prepare and utilize an herbal composition having the instantly claimed functional effect(s) other than the particular demonstrated herbal combinations (such as recited in original claim 8) for treating atopic eczema, non-atopic eczema and psoriasis (but not for treating any and all undefined atopic diseases).

Claim Rejections - 35 USC § 102

Claims 15 and 16 stand rejected under 35 U.S.C. 102(b) as being anticipated by Castleman (The Healing Herbs, 1991) for the reasons set forth in the previous Office action which are restated below.

A composition - including a pharmaceutical composition- comprising one or more herbal extracts/decoctions from among those recited is claimed.

Castleman teaches a therapeutic licorice extract - e.g., prepared as an orally-administered water decoction (which is the same or essentially the same preparatory method as that instantly disclosed), whereby licorice is the only herbal therein (see, e.g., page 239 -third paragraph under the heading *R_x for Licorice*). The water reads upon a pharmaceutically acceptable carrier/diluent. Please note that the instantly claimed R_f values would be inherent to such a licorice water extract decoction if the licorice water extract decoction were freeze-dried and subjected to chromatography parameters - as instantly claimed. Further, the reference licorice water decoction would inherently be in an amount effective to provide the instantly claimed functional effects.

Therefore, the reference is deemed to anticipate the instant claims above.

Again, with respect to the above USC 102 rejection, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed (e.g., to treat eczema or psoriasis), however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between

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the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting - see, e.g., MPEP 2112.

(Applicants should be aware that the same type of USC 102 rejection as discussed above could have been made over numerous other singular subset herbal extracts/decoctions from among those instantly claimed).

Applicants' arguments concerning the above rejection have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicant argues that claim 15 has been amended so as to no longer include a singular subset and that the limitations of original claim 8 has been added to claim 15. However, claim 15 - as currently drafted, still reads upon a singular subset including the reference licorice extract, as discussed above.

Claim Rejections - 35 USC § 103

Claims 1-4 and 9-16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan et al. (Lancet, 1992) and Whittle (GB 2,254,783) for the reasons set forth in the previous Office action which are restated below.

Sheehan et al. beneficially teach a Chinese herbal composition for treating atopic dermatitis comprising a standardized formulation containing a combination of the herbal extracts/decoctions recited in instant claim 1, as active ingredients therein. Sheehan et al. disclose that some of the herbals act as anti-inflammatory agents, some as anti-microbial agents, some as sedative agents, and at least one as an immunosuppressive agent (see entire document

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including page 14, under the heading *Treatment*, and the paragraph bridging the two columns on page 16). Sheehan et al. do not expressly teach using subsets/subcombinations of such herbal extracts/decoctions.

Whittle beneficially teaches herbal compositions for treating skin dermatological disorders such as eczema and psoriasis comprising various combinations of herbal extracts/decoctions which contain one or more of the instantly claimed herbal extracts/decoctions - as active ingredients therein, including a combination of *Paeonia rubra*, *Rehmannia glutinosa* and *Glycyrrhiza uralensis* (along with one additional herbal - i.e., *Ledebouriella sesloides*) - see, e.g., Example 3. Whittle also beneficially teaches that although Chinese medicine teaches that substantially all of the herbs within an herbal combination are necessary for activity, anti-eczema activity may reside in a restricted (limited) number of herbs (based upon their individual activity) within such combination - thus, unnecessary herbal material can be omitted therefrom. Whittle further discloses the activity provided by individual herbal ingredients - including the activities provided by various individual herbals from among those instantly claimed (see entire document including Abstract; page 2, line 26 - page 3, line 14; page 7, line 33 - page 8, line 10; Examples 1-11, and Table 1).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a pharmaceutical composition comprising one or more of the herbal ingredients disclosed by the cited references, as active ingredient(s) therein, for treating skin dermatitis (such as eczema or psoriasis) based upon the beneficial teachings provided therein with respect to the individual activities such herbals provide (as discussed by each of the cited references) and further based upon the beneficial provided by Whittle with respect to the

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use of restricted (limited) number of herbs (based upon their individual activity) within such combination. Please also note that the omission of an element and its function is obvious - e.g., if it is not desired and/or necessary (including, e.g., the omission of *Ledebouriella sesloides* from the herbal combination taught by Whittle in Example 3 therein). See, e.g., *Ex parte Wu*, 10 USPQ 2031, 1989 - MPEP 2144.04. The result-effective adjustment of particular conventional working conditions (e.g., using one or more particular combinations of herbal ingredients from among those instantly claimed, including one or more of the herbal extract/decoction ingredients beneficially taught by the cited references - based upon their well known individual activities against skin dermatitis disorders such as psoriasis and eczema, as disclosed therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicants' arguments concerning the above rejection have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicants argue that the presently claimed invention is a specific three-member group of the prior art teachings. However, for the reasons discussed above, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a pharmaceutical composition comprising one or

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more of the herbal ingredients disclosed by the cited references, as active ingredient(s) therein, for treating skin dermatitis (such as eczema or psoriasis) based upon the beneficial teachings provided therein with respect to the individual activities such herbals provide (as discussed by each of the cited references) and further based upon the beneficial provided by Whittle with respect to the use of restricted (limited) number of herbs (based upon their individual activity) within such combination. Please also note that the omission of an element and its function is obvious - e.g., if it is not desired and/or necessary (including, e.g., the omission of *Ledebouriella sesloides* from the herbal combination taught by Whittle in Example 3 therein). See, e.g., *Ex parte Wu*, 10 USPQ 2031, 1989 - MPEP 2144.04. The result-effective adjustment of particular conventional working conditions (e.g., using one or more particular combinations of herbal ingredients from among those instantly claimed, including one or more of the herbal extract/decoction ingredients beneficially taught by the cited references - based upon their well known individual activities against skin dermatitis disorders such as psoriasis and eczema, as disclosed therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Applicants further argue that two other patents have been granted to such subcombinations. However, the claims - as drafted (including with respect to "Rf value recitations concerning one or more of those components present in fractions") are not deemed to be of the same scope of the two previously allowed patents.

Please also note, as discussed *supra*, claim 15 is not limited to a three-member group.

In addition, see 01 May 2007 Interview Summary attached hereto.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Christopher R. Tate
Primary Examiner
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